Office of Internal Audit Services

UT Southwestern Medical Center

Medical Device Recall Credit Audit

Internal Audit Report 21:06

September 07, 2021

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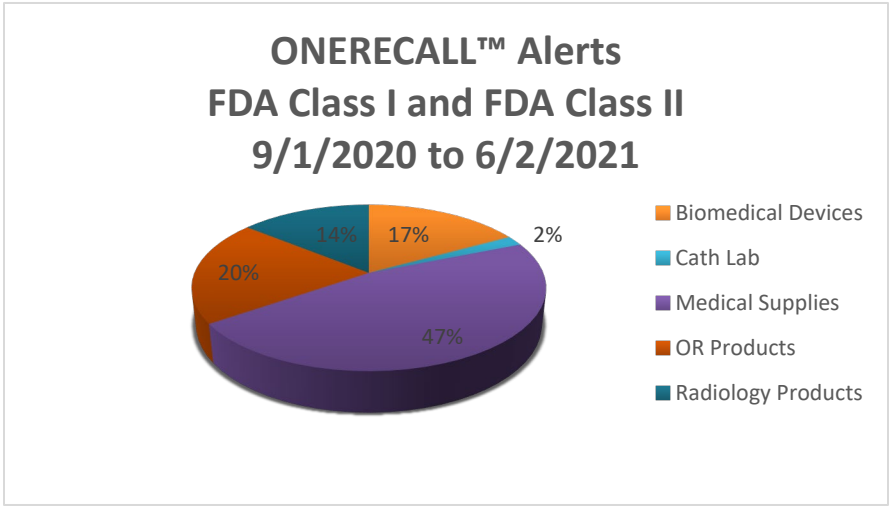
NOTE: In accordance with Government Code §552.139 *Exception: Confidentiality of Government Information Related to Security or Infrastructure Issues for Computers*, UT Southwestern Medical Center Office of Internal Audit Services is redacting a portion of this report (pages 5, 17 and 18) as it contains confidential information that relates to technology and is not subject to the disclosure requirements of the Texas Public Information Act.

Executive Summary

Background

Medical devices including instruments, apparatuses, machines, implants, or other similar or related articles are used to deliver excellent patient care. At times, the US Food and Drug Administration (FDA), US Department of Agriculture (USDA), a vendor, or a manufacturer can issue notifications related to recalled products which may have been identified as a potential risk to patients. The recalled products must be promptly identified, and recommended actions taken to ensure patient safety and quality of care are not compromised.



The illustration provides a summary of the types of FDA Class I and Class II recalls during the 9-month period of September 2020 through June 2021. A Class I recall is defined as 'a situation in which there is a reasonable probability the use or exposure to a volatile product will cause serious adverse health consequences or death.' Class II recalls are 'situations in which use of, or exposure to, a volatile product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.' UT Southwestern Hospitals, Hospital-based clinics and Ambulatory clinics use OneRecall™, a web-based system, to track internal and external notification processes for medical device recalls and/or alerts along with their resolution.

The Purchasing Department, a division of Supply Chain Management, oversees the OneRecall™ system. OneRecall™ sends notifications to Coordinators as assigned by functional area. The Coordinators and Responders within each functional area, clinic, or department are responsible for:

- Taking required recall actions, isolate products, and identify if the device has been used with a patient
- Coordinating the return of recalled product on hand with Purchasing or directly with the vendor
- Documenting results in OneRecall™

Epic Optime is the system used to document devices implanted in patients. Hospital Accounting applies applicable credits related to medical device recalls in PeopleSoft when credits are received from vendors.

Executive Summary

Scope and Objectives

The Office of Internal Audit Services has completed its Medical Device Recall Credit audit. This was a risk-based audit and part of the fiscal year (FY) 2021 Audit Plan. The audit scope period included medical device recall credit activities, specifically implants, from September 2020 through June 2021 at the Hospitals, Hospital-based clinics, and Ambulatory clinics. Overall objectives for the audit were to assess the adequacy and effectiveness of controls for management of medical device recall credits to ensure:

- Appropriate processes for notification, communication, and coordination of medical device recall related activities
- Effective processes for timely resolution of medical device recalls
- Adequate tracking and monitoring of vendor credits for medical device recalls
- Reliability of OneRecall™ and any other systems used in management of medical device recall credits

Audit procedures included interviews with stakeholders; review of policies, procedures, and other documentation; substantive testing; and data analytics. We conducted our examination according to guidelines set forth by the Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing.

Conclusion

Opportunities exist to strengthen operational processes and controls across Hospital, Hospital-based clinics, and Ambulatory clinics to identify and coordinate activities to ensure recalls affecting patients are addressed timely. Consistent processes and recall alert monitoring could help to ensure recalls are appropriately reviewed and resolved timely. Conducting periodic reviews of OneRecall™ Users & Facilities would help to ensure all appropriate people and facilities are being notified to address the recalls. There is a need for formal processes to be established for tracking and collecting credits due to University Hospital and Ambulatory clinics from vendors.

Included in the table below is a summary of the observations along with the respective disposition of these observations within the UT Southwestern internal audit risk definition and classification process. See Appendix A for Risk Rating Classifications and Definitions.

Priority (0)	High (1)	Medium (3)	Low (0)	Total (4)

Key observations are listed below.

- **#1 Implement Institutional Wide Process for Reporting Recalls Affecting Patients** – There is not an institutional process in place for Ambulatory and Hospital clinical areas to notify the Health System Patient team when recalled implants impact patients.

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- **#2 Enhance Medical Device Recall Monitoring to Ensure Alerts are Addressed Completely and Timely** – Medical device alerts are not consistently closed within five days from the assigned time as required by the hospital policy.

- **#3 Develop a System to Track and Collect Credits from Vendors for Medical Device Recalls** – A formal process is not in place to track credits owed for products returned to vendors due to recalls. University Hospitals and Ambulatory clinics rely on vendors to send credit memos, if applicable, and for Accounting to post credits to the appropriate account.

- **#4** - In accordance with Government Code §552.139 Exception: *Confidentiality of Government Information Related to Security or Infrastructure Issues for Computers*, UT Southwestern Medical Center Office of Internal Audit Services is redacting this information as it contains confidential information that relates to technology and is not subject to the disclosure requirements of the Texas Public Information Act.

Management has provided responses with planned action items to address the observations identified in the report. The responses, along with additional details for the key observations listed above, are included in the Detailed Observations and Action Plans Matrix section of this report.

We would like to take the opportunity to thank the individuals included in this audit for the courtesies extended to us and for their cooperation during our review.

Sincerely,

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Executive Summary

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Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: High **1. Implement Institutional Wide Process for Reporting Recalls Affecting Patients** There is not a formal institutional process in place for Ambulatory and Hospital clinical areas to ensure the Health System Patient team is notified when there are recalled implants that may have an impact on patients. Additionally, the device lot number information necessary to identify potentially impacted patients is inconsistently entered in EPIC Optime. Currently, it is optional for clinical teams to record implant lot numbers in EPIC Optime, which could result in missed opportunity to identify patients impacted by recalls. Based on review of Optime reports, 11,386 of 28,367 (40%) implanted products did not have lot numbers recorded in the Epic patient record. Approximately 4,400 (16%) were screws which typically do not have lot numbers. There have been no incidences where a patient did not receive appropriate follow up or care. Having a formal process in place reduces the risk of patients who could be impacted by recalls not being identified, notified or proper measures not being taken in response to the recall.	1. Update current policy regarding adverse events to reflect notifying the Health System Patient Safety team of medical device recalls which impact patients and require consultation with Medical Directors and patient providers. 2. Educate and train employees across clinical and hospital areas on process to notify the Health System Patient Safety team of medical device recalls with patient impact. 3. Consider requiring the entry of medical device lot numbers in EPIC Optime to identify recalled products. If device/lot number not available, provide set name or vendor ID via text option 4. Review the four identified patients and evaluate necessary actions in coordination with Medical Directors and patient providers. 5. Reeducate departments not to exchange or use products with affiliate organizations.	**1. Management Action Plan:** Health System Patient Safety team will add content to Patient Safety and Event Reporting – Hospital Policy (UHLD 05) and Event Reporting Policy (AMB 4.09) stating recalled products/devices that reached a patient must be reported as potential adverse events. Edits will be submitted to the Hospital and Ambulatory policy coordinators. **Action Plan Owner:** Manager, Health System Patient Safety **Target Completion Dates:** November 15, 2021 to make updates February 1, 2022 to get final approvals **2. Management Action Plan:** Health System Patient Safety team will provide education and reminders to the following audiences: • Urology clinic • Oral Maxillofacial Surgery clinic • Surgical Services

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
• Four patients had recalled implants and no further actions were taken. The implant for one of the patients was received in inventory from an affiliate organization and was not recorded in PeopleSoft Purchasing records.		**Action Plan Owners:** Manager, Health System Patient Safety Manager, Clinical Safety **Target Completion Date:** December 31, 2021 **3. Management Action Plan:** We will work with Operating Room leadership to assess the implications of requiring lot numbers to be entered in EPIC Optime. If the requirement is feasible, we will coordinate with IR to ensure the required field is updated in EPIC Optime. If device/lot number not available, provide set name or vendor ID via text option. **Action Plan Owners:** Manager, Surgical Materials Director, Surgical Services Administration Business Analyst Lead, IR Health Systems **Target Completion Date:** November 30, 2021

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
		4. Management Action Plan: Health System Patient Safety team opened event reports to determine whether the four identified patients impacted by recalls require notification based upon discussions with the associated clinical departments. **Action Plan Owner:** Manager, Clinical Safety **Target Completion Date:** Completed **5. Management Action Plan:** We will provide refresher training to departments regarding the avoidance of exchanges and use of medical devices between affiliate organizations. **Action Plan Owners:** Manager, Surgical Materials Director, Surgical Services Administration **Target Completion Date:** November 1, 2021

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium **2. Enhance Medical Device Recall Alert Monitoring to Ensure Alerts are Addressed Completely and Timely** Medical device alerts are not consistently closed within five days from the assigned time as required by the hospital policy. However, the timeline is not clear because of possible reassignments of Coordinators. As of June 2021, 694 (18.4%) alerts in OneRecall™ had been open from 30 days to six months. 259 of the open alerts were identified as urgent and 189 had probable Purchase Order matches within OneRecall™. Approximately 95% of the open alerts are related to Ambulatory clinics. Additionally, Ambulatory Clinical Operations do not currently have a formal policy and procedures in place to address medical device recalls. Without a formal policy in place, medical device recall alerts may not be addressed appropriately resulting in increased risk of inaccurate reporting to external agencies and patient care impact. Reasons for delays included: • A procedure was not consistently followed to escalate open alerts. • Employees assigned to the Coordinator role were not reviewing or closing alerts, because they did not know it was part of their role.	1. Consider requiring comments within OneRecall™ to notate details, such as quantities and lots removed. 2. Consider assessing alerts to determine criteria and risk factors for defining required timelines for closing alerts. Update the required timeframes for assigning and closing all OneRecall™ alert types. 3. Provide refresher training on updated alert closing procedures in OneRecall™ for assigned Responders and Coordinators. 4. Update and approve Ambulatory Recall Response Policy (AMB 6.13) to reflect the updated process related to recalled products to include use of OneRecall™ and creating event reports when recalls with patient impact are identified. 5. Distribute policy across Ambulatory clinics and ensure training has occurred.	**1. Management Action Plan:** We will evaluate and update the Hospital and Ambulatory policies to include verbiage to recommend comment details when closing alerts, such as quantities and lot numbers. **Action Plan Owners:** Assistant Vice President Supply Services, Hospital Administration, University Hospitals Director, Surgical Services Administration Director, Ambulatory Clinical Initiatives Director Purchasing, Supply Chain Management **Target Completion Dates:** November 15, 2021 to initiate meetings as a group to discuss December 30, 2021 to update the Hospital and Ambulatory policies February 15, 2022 to approve updated Hospital and Ambulatory policies **2. Management Action Plan:** We will evaluate the timelines and criteria for closing alerts within OneRecall™ based on the urgency and recall types. We will update the Hospital and Ambulatory policies to reflect the updated timelines.

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
• Coordinators were unsure how to close alerts in OneRecall. • Responders may have addressed alerts, but the Coordinators did not close the alerts. Untimely review and closing of recall alerts increases the risk of noncompliance with external agencies and missed opportunity for applicable credits, as well as increased risk of not addressing patient safety.		Any updated information will be communicated to all users. **Action Plan Owners:** Assistant Vice President Supply Services, Hospital Administration, University Hospitals Director, Surgical Services Administration Director, Ambulatory Clinical Initiatives Director Purchasing, Supply Chain Management **Target Completion Dates:** November 15, 2021 to initiate meetings as a group to discuss December 30, 2021 to update the Hospital and Ambulatory policies February 15, 2022 to approve updated Hospital and Ambulatory policies 3. **Management Action Plan:** We will update Hospital and Ambulatory policies to include refresher training for OneRecall™ users. We will communicate across the institution the updated timeframes to include the importance of addressing alerts, notifying or transferring to others as well as responsibilities for monitoring.

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
		Action Plan Owners: Assistant Vice President Supply Services, Hospital Administration, University Hospitals Director, Ambulatory Clinical Initiatives Director, Surgical Services Administration Director Purchasing, Supply Chain Management **Target Completion Dates:** November 15, 2021 to initiate meetings as a group to discuss December 30, 2021 to update the Hospital and Ambulatory policies February 15, 2022 to approve updated Hospital and Ambulatory policies **4. Management Action Plan:** Ambulatory Management will review and revise current policy to address the process and updates on how to handle recalled medical products. **Action Plan Owner:** Director, Ambulatory Clinical Initiatives **Target Completion Dates:** December 30, 2021 to update February 15, 2022 to approve

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
		5. Management Action Plan: Once the policy has been finalized, Ambulatory Management will ensure policy has been communicated. **Action Plan Owner:** Director, Ambulatory Clinical Initiatives **Target Completion Date:** February 28, 2022

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium **3. Develop a System to Track and Collect Credits from Vendors for Medical Device Recalls** A formal process is not in place to track credits owed for products returned to vendors due to recalls. University Hospitals and Ambulatory clinics rely on vendors to send credit memos, if applicable, and for Accounting to post credits to the appropriate account. Without proper monitoring of vendor returns and credits, there is a risk credits due to UT Southwestern are not identified and collected. Specifically: • Procedures are not in place to guide the different areas and central functions on how to address, track, and monitor medical device returns and credits. • Controls are not in place to ensure all recalled medical devices are returned to vendors for replacement or credit. • Recalled products which may not have an equivalent replacement are sent back to vendors and Clinical Departments and Hospital Accounting are not aware if applicable credits are owed.	1. Update the Return to Vendor (RTV) PeopleSoft process to include guidelines for returns associated with recalls for credit or replacement across Hospitals, Hospital-based clinics, and Ambulatory clinics for open and closed Purchase Orders (POs). 2. Once the guidelines are updated and finalized, update the Purchasing and AAIR websites and communicate and educate across the institution. 3. Utilize monthly tracking report to confirm receipt of expected credits for returned recalled products. Apply credit memos received for closed POs to correct department accounts as applicable.	**1. Management Action Plan:** We will update the RTV process to include the returns associated with recalls for credit or replacement across the institution for open and closed Purchase Orders. **Action Plan Owners:** Director, PeopleSoft Financial & Supply Chain, IR-AAIR Administrative Systems Director, Purchasing, Supply Chain Management **Target Completion Date:** December 15, 2021 **2. Management Action Plan:** We will upload the updated guidelines and how-to steps on the Purchasing and AAIR websites and share with the institution. **Action Plan Owners:** Director, PeopleSoft Financial & Supply Chain, IR-AAIR Administrative Systems Director, Purchasing, Supply Chain Management **Target Completion Date:** December 31, 2021

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
		3. **Management Action Plan:** We will create a query to track RTVs. Accounting will periodically use the query to review expected credits. **Action Plan Owners:** Director PeopleSoft Financial & Supply Chain, IR-AAIR Administrative Systems Assistant Controller, Financial Services **Target Completion Date:** December 15, 2021

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium **4.** In accordance with Government Code §552.139 *Exception: Confidentiality of Government Information Related to Security or Infrastructure Issues for Computers*, UT Southwestern Medical Center Office of Internal Audit Services is redacting this information as it contains confidential information that relates to technology and is not subject to the disclosure requirements of the Texas Public Information Act.	In accordance with Government Code §552.139 *Exception: Confidentiality of Government Information Related to Security or Infrastructure Issues for Computers*, UT Southwestern Medical Center Office of Internal Audit Services is redacting this information as it contains confidential information that relates to technology and is not subject to the disclosure requirements of the Texas Public Information Act.	In accordance with Government Code §552.139 *Exception: Confidentiality of Government Information Related to Security or Infrastructure Issues for Computers*, UT Southwestern Medical Center Office of Internal Audit Services is redacting this information as it contains confidential information that relates to technology and is not subject to the disclosure requirements of the Texas Public Information Act.

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response

Appendix A – Risk Classifications and Definitions

As you review each observation within the Detailed Observations and Action Plans Matrix of this report, please note that we have included a color-coded depiction as to the perceived degree of risk represented by each of the observations identified during our review. The following chart is intended to provide information with respect to the applicable definitions and terms utilized as part of our risk ranking process:

	Degree of Risk and Priority of Action	
Risk Definition- The degree of risk that exists based upon the identified deficiency combined with the subsequent priority of action to be undertaken by management.	**Priority**	An issue identified by Internal Audit that, if not addressed immediately, has a high probability to directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.
	High	A finding identified by Internal Audit that is considered to have a high probability of adverse effects to the UT institution either as a whole or to a significant college/school/unit level. As such, immediate action is required by management in order to address the noted concern and reduce risks to the organization.
	Medium	A finding identified by Internal Audit that is considered to have a medium probability of adverse effects to the UT institution either as a whole or to a college/school/unit level. As such, action is needed by management in order to address the noted concern and reduce the risk to a more desirable level.
	Low	A finding identified by Internal Audit that is considered to have minimal probability of adverse effects to the UT institution either as a whole or to a college/school/unit level. As such, action should be taken by management to address the noted concern and reduce risks to the organization.

It is important to note that considerable professional judgment is required in determining the overall ratings presented on the above pages of this report. Accordingly, others could evaluate the results differently and draw different conclusions. It is also important to note that this report provides management with information about the condition of risks and internal controls at one point in time. Future changes in environmental factors and actions by personnel may significantly and adversely impact these risks and controls in ways that this report did not and cannot anticipate.